

**For Immediate Release**

### **MEDICAL DEVICE INDUSTRY GETS A BOOST FROM YEUNGNAM, KOREA**

**George Town, PENANG. 12 November 2012** - The demand for clinical trial and in-vitro biocompatibility testing has been increasing as the medical devices manufacturing industry moves up the value chain into research and development (R&D) activities.

To support the growth of the medical devices sector, Info Kinetics Sdn Bhd and Clinical Trial Centre for Medical Devices of Yeungnam University Hospital from South Korea are signing a Memorandum of Understanding (MOU) to formally establish co-operation and collaboration in medical device testing and clinical trials, e.g. *in-vitro* biocompatibility testing according to ISO 10993, toxicology studies, leaching studies and medical devices clinical trials according to ISO 14155. This collaboration will lay the foundation for the first fully-structured medical device clinical trials centre in the Northern Corridor Economic Region (Koridor Utara).

This MOU provides a platform for technical collaboration for compliance with Organization for Economic Co-operation and Development (OECD)'s Good Laboratory Practice (GLP). It will also provide opportunities for technical internship placement between the two institutes. In addition, both parties will collaborate as bidding partners in a global trial proposal.



(L to R): Prof Ahn Sang Ho, Dato' Redza Rafiq, Dr Lee Toong Chow

The Director of Clinical Trial Centre for Medical Devices of Yeungnam University Hospital from South Korea, Prof Anh commented, "Although South Korea has been an OECD member country since 1995, there are very few OECD GLP laboratories, especially for medical device testing. The best strength offered by Info Kinetics is their 6 years of OECD GLP accreditation status."

Koridor Utara has been growing steadily, with more and more medical devices companies setting up operations in the region. Based on an industry survey conducted by the Association of Malaysian Medical Industries (AMMI) last year, Koridor Utara has already established itself as the hub for medical device clusters in Malaysia; and has been recognised as the most integrated manufacturing cluster within ASEAN.

The companies with significant manufacturing facilities in Koridor Utara include Ambu, Bard, B.Braun, Covidien, Symmetry Medical, St Jude Medical, Teleflex; and a home-grown company Vigilenz; which produces pacemakers, catheters, safety intravenous cannula and needles, sutures, orthopedic products, medical electrodes, dialyzers and surgical gloves.

In order to move up the value chain from manufacturing of medical device to high-value R&D activities, there is an urgent demand to have biocompatibility, biological evaluations and clinical trial activities.



The Chief Executive of the Northern Corridor Implementation Authority (NCIA), Dato' Redza Rafiq said: "The government is very supportive of this collaboration as it marks a significant milestone in bringing science and technology skill sets to a new level by leveraging on what we have built over the past 40 years of industrialization in the north of Malaysia, starting with the electronics industry."

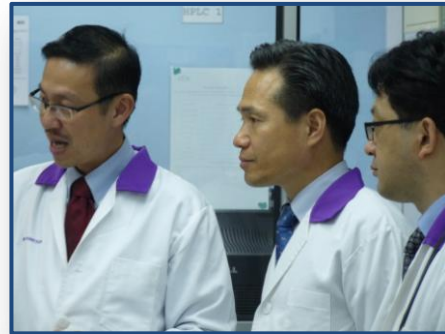
"The collaboration in clinical trial and in-vitro biocompatibility testing will be able to support various Entry Point Projects (EPPs) for 'Healthcare and Medical Devices' under 'Healthcare National Key Economic Area' (NKEA) announced last year. The 7 EPPs launched in 2011 are expected to bring in some RM 17.1 billion in revenue and a gross national income of RM 11.4 billion, as well as creating 86,000 employment opportunities by the year 2020."

Mr. Hitendra Joshi, Chairman of Association of Malaysian Medical Industries said: "The collaboration is a timely initiative and in line with AMMI Strategy 2015 to promote R&D, innovation and shared services for the growth of the medical devices industry in Malaysia."



In today's MOU, initiating this collaboration is Prof. Sang-Ho Ahn, Director of Clinical Trial Centre for Medical Devices of Yeungnam University Hospital from South Korea and Dr. Lee Tong Chow, Managing Director of Info Kinetics Sdn Bhd. This MOU is witnessed by Dato' Redza Rafiq, Chief Executive of the Northern Corridor Implementation Authority (Koridor Utara).

Also present are Dr. Mary Quah, CEO of LohGuanLye Specialists Centre and Mr. Hitendra Joshi, Chairman of the Association of Malaysian Medical Industries (AMMI).



#### **About Info Kinetics Sdn Bhd**

Info Kinetics offers services from Phase I to IV clinical trials since 2001. This includes bioequivalence and bioavailability studies. The company is capable of rapid trial subject recruitment and provides efficient and effective trial coordination in this region in trials involving all therapeutic areas. Our services are proven to be cost-effective as a result of improved trial coordination. The laboratory services, eg. Bioanalytical, preclinical toxicokinetics, analytical method validation, stability study conducted by Info Kinetics adheres to internationally-recognized quality standards (OECD GLP, MS ISO/IEC 17025). For more information on Info Kinetics, please log on to <http://info-kinetics.com/>

#### **About Clinical Trial Centre for Medical Devices (MDCTC) of Yeungnam University Hospital of South Korea**

Clinical Trial Centre for Medical Devices (MDCTC) of Yeungnam University Hospital was designated as a clinical trial centre for medical devices since November 2008 to carry out verification of safety and efficiency for medical devices and contributes to the development of high-tech medical devices. For more information on MDCTC, please log on to <http://emdctc.org/eng/index.html>

**Northern Corridor Implementation Authority (NCIA)** is the statutory body responsible for establishing directions, policies and strategies in relation to Koridor Utara development programmes. Incorporated in June 2008, NCIA's mandate by the Malaysian government is to promote and accelerate the development of Koridor Utara into a world-class economic region and a choice destination for investment, work and living.

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